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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/011,867 | 12/05/2001 | Clifton A. Alferness | 1931-7-3 | 5299 |

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/011,867 | Applicant(s) ALFERNES ET AL. | |
| | Examiner Urmi Chattopadhyay | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,13,14 and 23-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-43 is/are allowed.
- 6) ☒ Claim(s) 4,5,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Request for Reconsideration filed 6/16/04 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 4, 5, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. (USPAP 2001/0018611 as cited in applicant's IDS) in view of Pai et al. (USPAP 2003/0078465 as cited in applicant's IDS) and Langberg et al. (USPN 6,402,781 as cited in applicant's IDS).

Solem et al. discloses a device for effecting mitral valve annulus geometry of a heart with all the elements of claims 4, 5, 13 and 14, but is silent to the first or second anchor being self-expanding and to a lock that locks the cable on the second anchor. See Figure 13 and [0054] for a first anchor (23) configured to be positioned within and fixed to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a cable (27) fixed to the first anchor and extending proximally from the first anchor within the heart, and a second anchor (25) configured to be positioned in and fixed in the heart proximal to the first anchor and arranged to slidably receive the cable (27). Geometry of the mitral valve is effected when the first and second

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anchors are fixed within the heart and the cable is proximally drawn, thereby reducing the space between the anchors. Pai et al. teaches a tensioning device positioned in the coronary sinus, wherein the device includes proximal and distal anchors (32) that are self-expanding in order to anchor the device to and within the vessel. See [0085] and [0100]. Also, the anchors of Solem et al. are in the form of stents and it is old and well known in the art that stents can be self-expanding. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Pai et al. to modify the device of Solem et al. by making the first and second anchors self-expanding. Langberg et al. teaches a percutaneous mitral annuloplasty device that is positioned in the coronary sinus, wherein the device includes a lock to lock a forming element to the proximal end of the device in order to maintain sufficient tension in the forming element to reconfigure the device to a remodeling orientation. See Figure 2 and column 8, lines 47-58. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Langberg et al. to modify the device of Solem et al. by including a lock on the second anchor in order to lock the cable to the second anchor in sufficient tension to maintain the reduced spacing between the anchors.

Allowable Subject Matter

4. Claims 23-43 are allowed.

Response to Arguments

5. Applicant's arguments filed 6/16/04 have been fully considered but they are not persuasive. Applicant argues that the examiner's conclusion (the invention recited by claims 4,

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5, 13 and 14 would have been obvious to one of ordinary skill in the art) is not based on any teaching or suggestion in the references themselves that the elements can or should be combined in the manner recited in the above claims. The examiner disagrees.

6. The above rejection clearly provides the motivation taught by Pai et al. to make the anchors of a device placed in the coronary sinus self-expanding. That motivation is to anchor the device to and within the vessel; see [0100]. Therefore, the motivation to make the anchors of Solem et al. self-expanding is to anchor the device to and within the vessel. The anchors of Solem et al. are certainly capable of being made self-expanding without destroying the functioning of the anchors or the device as a whole. No evidence has been provided by the applicant to prove otherwise.

7. Additionally, obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the anchors of Solem et al. are in the form of stents, and it is old and well known in the art that stents can be self-expanding in order for the stent to change from a compressed delivery configuration to a deployed expanded configuration within a lumen without requiring a separate balloon catheter or other expansion means. Therefore, the motivation to make the stent anchors of Solem et al. self-expanding is found in the knowledge generally available to one of ordinary skill in the art. Applicant has not argued against examiner's contention that self-expanding stents are old and well known in the art.

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8. The above rejection also clearly provides the motivation taught by Langberg et al. to include a lock on the proximal end of an annuloplasty device placed within the coronary sinus. That motivation is to lock a forming element to the proximal end in order to maintain sufficient tension in the forming element to reconfigure the device to a remodeling configuration; see column 8, lines 47-58. Therefore, the motivation to include a lock to the proximal end of the device of Solem et al., which is the second anchor, is to lock the cable to the second anchor to maintain sufficient tension in the cable to reconfigure the device to a remodeling configuration. The second anchor of Solem et al. is certainly capable of including a lock that locks the cable thereon without destroying the functioning of the second anchor or the device as a whole. No evidence has been provided by the applicant to prove otherwise.

9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

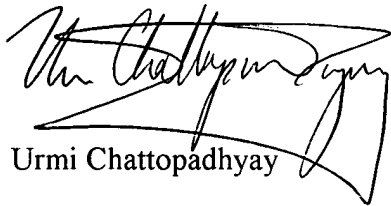
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

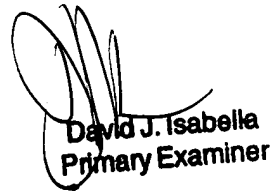
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner